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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,209	10/16/2006	Samuel Waksal	13821/48902	2944

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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,209	WAKSAL, SAMUEL	
	Examiner	Art Unit	
	SEAN E. AEDER	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,9,11 and 22-28* is/are pending in the application.

4a) Of the above claim(s) *24,25 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,9,11,22,23,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/24/08; 5/19/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 4/15/08 in response to the Office Action of 10/10/07 are acknowledged and have been entered.

Claims 22-28 have been added by Applicant.

Claims 1, 2, 9, 11, and 22-28 are pending.

Claims 24, 25, and 28 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention. Note that claims 24, 25, and 28 are drawn to unelected species (elected species are "ABX-EGF" and "OSI-774"; "bevacizumab" is a rejoined species).

Claims 1 and 9 have been amended by Applicant.

Claims 1, 2, 9, 11, 22, 23, 26, and 27 are currently under examination.

Rejections Withdrawn

The rejections under 35 U.S.C. 112, second paragraph, are withdrawn.

The rejections under 35 U.S.C. 112, first paragraph, are withdrawn.

Response to Arguments

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 11 remain rejected and newly added claims 22, 26, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Alitalo et al (US 2002/0164667 A1; 11/7/02), as evidenced by Fong et al (Cancer Research, 1/1/99, 59:99-106) for the reasons stated in the Office Action of 10/10/07 and for the reasons set-forth below.

The Office Action of 10/10/07 contains the following text:

"The claims are drawn to a method of inhibiting an RTK in a mammal comprising administering an extracellular RTK antagonist and an intracellular RTK antagonist. As evidenced by Fong et al, SU5416 is an intracellular VEGFR antagonist (see right column of page 99, in particular).

Alitalo et al teaches a method of treating tumor growth or angiogenesis in a mammal by inhibiting VEGFR in a mammal comprising administering an extracellular VEGFR antagonist, such as an anti-VEGFR antibody and/or a peptide that functions as an extracellular VEGFR antagonist by inhibiting VEGF from binding VEGFR, and an intracellular VEGFR antagonist, such as SU5416, to the mammal (see paragraphs 60, 75, 135, 208, in particular). Alitalo et al teaches a method further comprising administering an antineoplastic agent (see paragraph 62, in particular)."

In regards to newly-added claim 22, the anti-VEGFR antibodies and peptides of Alitalo et al are biological molecules. In regards to "VEGF-2", Alitalo et al teaches "VEGFR-2" as a VEGFR family member whose suppression suppresses growth of several tumor lines (paragraph 32, in particular). Alitalo et al further teaches antibodies against VEGFR-2 entering clinical trials (paragraph 32, in particular), and that inhibitors of VEGF family member have tremendous potential as therapeutics aimed at inhibiting neovascularization in order to inhibit or eliminate a variety of neoplastic disorders or cell proliferative disorders (paragraph 34, in particular). In regards to newly added claims

26 and 27, as evidenced by Arora et al (J Pharmacol Exp Ther, December 2005, 315(3):971-979), SU5416 of Alito et al is a small molecule that performs as an antagonist to tyrosine kinases such as VEGFR-2 by competing with ATP for binding to intracellular catalytic domains (see abstract of Arora et al, in particular). Therefore, Alitalo et al teaches a method of treating tumor growth or angiogenesis by inhibiting VEGFR-2 in a mammal comprising administering an extracellular VEGFR-2 antagonist (antibodies against VEGFR-2 that inhibit binding of VEGF to VEGFR-2), an intracellular VEGFR-2 antagonist that is a small molecule which competes with ATP for binding to the intracellular domain of VEGFR-2 (SU5416), and an antineoplastic agent to the mammal.

In the Reply of 4/15/08, Applicant states that the rejection is moot in view of amendments.

The amendments to the claims and the arguments found in the Reply of 4/15/08 have been carefully considered, but are not deemed persuasive. In regards to the statement that the rejection is moot in view of amendments, Applicant has not pointed-out any specific reason why the rejection is moot in view of amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 9, and 11 remain rejected and newly-added claims 22, 23, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alitalo et al (US 2002/0164667 A1; 11/7/02) as applied to claims 1, 2, 11, 22, 26, and 27 above, and further in view of Rosen (Cancer Control, Mar-Apr 2002, 9(2) (supplement): 36-44), for the reasons stated in the Office Action of 10/10/07 and for the reasons set-forth below.

The Office Action of 10/10/07 contains the following text:

"The teaching of claims 1, 2, 8, and 11 by Alitalo is discussed above. Alitalo et al does not specifically teach a method comprising administering the extracellular VEGFR antagonist bevacizumab (claim 9). However, this deficiency is made up in the teachings of Rosen.

Rosen teaches a method of treating tumor growth or angiogenesis by administering bevacizumab, an anti-VEGFR monoclonal antibody produced by Genentech (San Francisco, CA) (right column of page 41, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to perform the method of treating tumor growth or angiogenesis in a mammal by inhibiting VEGFR in a mammal taught by Alitalo et al with the extracellular VEGFR antagonist bevacizumab because Alitalo et al teaches performing said method with an anti-VEGFR antibody produced by Genentech (San Francisco, CA) (see paragraph 208, in particular) and Rosen teaches bevacizumab is an anti-VEGFR antibody produced by Genentech (San Francisco, CA) that is used to treat tumor growth or angiogenesis (right column of page 41, in particular). One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for performing the method of treating tumor growth or angiogenesis in a mammal by inhibiting VEGFR in a mammal taught by Alitalo et al with the extracellular VEGFR antagonist bevacizumab because Alitalo et al teaches performing said method with an anti-VEGFR antibody produced by Genentech (San Francisco, CA) (see paragraph 208, in particular) and Rosen teaches bevacizumab is an anti-VEGFR antibody produced by Genentech (San Francisco, CA). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results."

In regards to newly-added claim 23, bevacizumab taught by Rosen is a monoclonal antibody that binds VEGFR-2 (as acknowledged by instant claim 9).

In the Reply of 4/15/08, Applicant states that the rejection is moot in view of amendments.

The amendments to the claims and the arguments found in the Reply of 4/15/08 have been carefully considered, but are not deemed persuasive. In regards to the statement that the rejection is moot in view of amendments, Applicant has not pointed-out any specific reason why the rejection is moot in view of amendments.

Summary

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Examiner, Art Unit 1642